Mexico, D.F. April 3rd, 2003.

Dockets and Management Branch (HFA 305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N- 0278; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Federal Register 5428 (February 3, 2003)

The National Agricultural Council (NAC) is conformed by near 150 Members; it's partners are Agricultural and Cattle Producer's Organizations of Mexico.

As associates has Farm Services Suppliers Organizations and Agricultural and Livestock industry enterprises, who enforces and compliment sectorial activities. Our organism is the most important at national level; it's members contribute with 70% of Gross Domestic Agricultural Product, 80% of Gross Domestic Livestock Product, 70% of Gross Domestic Agricultural Industry related Products and 75% of Total Agricultural Exports.

The NAC strongly believes that enhanced security of the U.S. food supply is crucial for the continued safety of U.S. consumers and their confidence in the food imports.

Attach to this letter we send comments about the Bioterrorism Act 's Title III section 307, received for some of our members.

The NAC wishes to reiterate that we fully support measures to ensure that we can deliver food safe, secure produce to American consumers. However, we do not feel that the current prior notice proposal will be an effective mechanism to accomplish the desired objectives of the FDA.

Our members stands ready to work with the FDA in implementing a system that would fully take advantage of existing resources and in sharing our first hand knowledge of current exporting procedures to help the FDA to develop an efficient system that could enhance security of the U.S. Food supply system.

Sincerely,

Armando Paredes Arroyo Loza
President

Alfredo Moises Ceja
Vicepresident, Foreign Trade

02N-0278

C 108

Comments of the National Agricultural Council about
The Bioterrorism Act

I.- General Comments for the Food and Drug Administration (FDA) Authority

1.1. The United States Government has the right to establish its own laws; however we appeal for this Law to give us as country a **Most Favored Nation** treatment, far from becoming a non tariff barrier for the Mexican exports, and to comply with the **North American Free Trade Agreement (NAFTA)** rules.

1.2. This Law enforcement **must not result** in a **slower** customs inspection process that could delay the delivery of merchandise, consequently affecting the **perishable products quality**, the **timeliness of its delivery**, the **shelf life** required by the buying companies, and it could become a **non tariff barrier to trade** that may transgress NAFTA provisions and World Trade Organization (WTO) agreements.

1.3. Provided that there is an **agri-food products export tradition** from Mexico to the U.S. under NAFTA, we propose to set up a **cooperation outline** between both countries **to ease** the compliance of this Law provisions. This could be particularly applied to companies who have a good record of integrity and fulfillment similar to that of the **Business Anti-Smuggling Coalition (BASC) Program**.

1.4. We propose the **source inspection**, and in fact there are operating verification programs at source currently working, for **fresh fruits and vegetables** exports for them to comply with U.S. phytosanitary regulations, and which are 100% inspected in their production, packing, certification and export processes by **USDA employees**. We consider the FDA can make use of this operating system.

1.5. About the **confidentiality of the information** contained in the facilities registration and provided by the companies, there must be a guarantee that it must be **strictly** kept that way, avoiding risks of exposure in handling this information.

1.6. There must also be provided guarantees of the **sustainability and effectiveness** of the computerized system to avoid delays and unintentional faults about regulations.

II.- Particular Comments for the Food and Drug Administration (FDA) Authority

2.1. Vegetables Producers and Exporters (CAADES point of view)

2.1.1. CAADES and AALPUM[1/]

Section 307 Title III Prior Notice of Imported Food

- ✓ On behalf of all the vegetable producers and exporters of the Mexican state of Sinaloa affiliated to CAADES Sinaloa, A.C., we would like to express our opposition to the current form of the proposed rule related to Section 307 Title III of the U.S. Bioterrorism Act.

Current Trade and Government Practices

- ✓ Growers from the state of Sinaloa have been exporting fresh produce to consumers in the United States for nearly a century. We fully accept and appreciate our responsibility and opportunity to provide a stable supply of fresh vegetables to help ensure healthier diets for U.S. consumers. This commitment can be seen in the way growers of Sinaloa have actively worked with U.S. government agencies over the past decades to increase the quality and safety of our product to best protect the interests of U.S. citizens and consumers.

- ✓ Every season our growers provide about 800 thousand tons of fresh winter vegetables during the months of December through June to the United States. Due to the geographic location of our state, the closest point of entry to the U.S. and Canadian markets is Nogales, Arizona, and our growing areas are located from 450 to 750 miles from this port entry.

- ✓ Once the trucks leave our packing plants, they take from 10 to 18 hours drive to arrive to Nogales distributing facilities, depending on the location of the packing house. In the bordering City of Nogales, Sonora, the trucks can clear USDA quality inspections, as well as weight certification, at our facilities (CAADES Compound) located close to the Mexican Customs.

- ✓ Nogales has been by far, the most important point of entry for Mexican fresh fruits and vegetables. Around 53% of the 165 thousand trucks that all regions in Mexico exported last year, crossed through Nogales, while only 29% used all the extended south Texas borders, and 18% used the ones in California.

- ✓ Because of the amount of transactions made during the season, Nogales Arizona is the second most important point of entry of fresh produce to USA after Philadelphia (when including the combined totals from the various docks

[1/] CAADES = Confederation of Agricultural Associations of Sinaloa State
AALPUM = Local Agricultural Association of Table Grape Producers

in New Jersey, Pennsylvania, and Delaware). In the last 10 years, Nogales jumped from about 50 thousand trucks in a year to more than 83 thousand. This rate of increase is more than 60%.

Importance of Inter Agency Cooperation

- ✓ According to information presented by the Highway Patrol in Mexico, the border truck traffic for export of refrigerated trucks with perishables in Nogales during the peak of the season reached 1,139 trucks daily, plus 228 with hard freight, 53 of empty ones additionally and 14 of others.

- ✓ At a volume of more than 1,100 trucks with perishables in a given operating day of 8 hours of service from the various federal agencies on both sides of the border, it will require the clearing of more than 120 trucks per hour or more than 1 truck for crossing every 30 seconds. The U.S. and Mexican Customs have made a big effort to accomplish the goal of processing all the trucks. They have done this by methods including promoting as much interagency cooperation as possible and extending their respective working hours of the personnel.

- ✓ Nonetheless, the lack of better infrastructure will create delays if any agency working at the border is not in coordination with the other agencies. Any action that creates significant increases in traffic congestion without any real gain in the enforcement capabilities of inspection agencies will be a hindrance to the industry and will negatively impact the coordination activities with other government inspection agencies.

Our opinion is that the Proposed Rule Will Hinder Food Security and Food Supply

- ✓ At the present time, it is not unusual for trucks to wait in a line that can reach 2 or 3 miles. This delay makes difficult on even impossible to know the crossing time as requested by the FDA proposal. Furthermore, this will result in the duplication of submissions that will result in a significant number of trucks that will require to spend the night parked on unsecured highway, increasing the risk of intentional contamination by someone who wishes to harm the U.S.

- ✓ It is better for both the U.S. agencies and the importers, to have the product, as soon as possible, at secured importer's warehouses located just across the border, rather than idling on the side of unsecured highways. Given the lack of infrastructure and resources at the border to handle the flow of trucks during the produce season, the waiting time to cross can take from several minutes to 12 hours.

Shipment Contents Not Known by Noon on the Previous Day

- ✓ The FDA is proposing the prior notice requirement for noon the day before product physically enters the United States. This will require important government resources that already work to ensure food safety. Creating a duplicate data submission system that is not linked to the U.S. Customs database will hinder the communication efforts of government agencies regulating the border.

- ✓ If this proposal is implemented as pointed out, it will create a serious disruption in the trade and marketing commitments between distributors/importers and receivers. The growers typically harvest their product in the morning and pack and cool the product in the afternoon. Produce may stand in the cool room for about 6 hours or more to release the heat from the field and lower the temperature to a suitable shipping condition.

- ✓ By late afternoon or evening, the shipments leave to the border to arrive the following morning to be ready to accomplish the USDA inspection when required, by a marketing order or by the importer. Almost everything that the grower ships would not meet the 12:00 prior day requirement, so importers would be forced to wait up an additional 32 hours to fill customer's orders. Because the highly perishable nature of produce, customers would not want to wait for produce that has declined in appearance and quality and increased in ripeness to a point that, some of it, may become overripe before they have been able to sell it.

- ✓ The grower, not the importer, decides on a day-to-day basis, the amount of product that will be shipped to Nogales. This in turn will depend of the growing conditions, the age of the plant, the weather, the market trend and the expected price, so neither the grower and/or the importer can predict the exact amount of produce that will be harvested and shipped on a given day.

Industry and FDA Should Work to Increase Food Security

- ✓ CAADES and its members recognize the efforts that the U.S. agencies are implementing to ensure and protect the American consumers. We fully support that effort, and are willing to cooperate in whatever would be reasonable to accomplish that goal. However we do not believe that the current prior notice proposal will be suitable to the existing export and marketing practices with perishable products imported from Mexico.

- ✓ More importantly, we feel that this proposal in its current form would actually increase the risk to public health from bioterrorism.

- ✓ We apply USDA Authorities for their consideration about the particular nature of the trade of perishable products, and fully recommend FDA to implement a system that can allow its agents to fully comply their duties in a more secured

importer's warehouse, across the border, instead of U.S. Customs Compound, having hundreds of trucks standing in line, sometimes overnight, on the road waiting to cross.

- ✓ The use of the existing data sent to Customs and FDA will minimize the risk of intentional contamination, but at the same time, it will allow the industry provide the prior notice required within a suitable period of time. We are committed to work with Customs and the FDA to facilitate the transfer of information related to adjustments or changes with regard to the original information submitted.

2.2. Fruits Producer and Exporters

2.2.1. EMEX[1/]

Section 307 Title III Prior Notice of Imported Food

- ✓ USDA has a registration of all the shipments that we send to the United States of America, before they leave the packing facilities. This registration can have a double purpose; it can be copied to the FDA and to the USDA.

- ✓ All the facility members of EMEX have an USDA officer, who can make the inspection of the product required by FDA and assure that the product is not hazardous to the human health. The USDA officer places a seal on the container door, which only Mexican or United States Officers can violate. If the Mexican Government breaks the seal, USDA is informed.

- ✓ We believe that it is really important to tighten communication between the USDA and FDA in Mexico. This will provide the necessary information to the USDA officers to assure that they are also fitting the FDA requirements.

- ✓ We have a facility really close to the Nogales and Pharr Port of Entry were there is an USDA officer that can inspect the product that has a broken seal. That officer also can make the job required by the FDA.

Shipment Detention

- ✓ In case of detention of the shipment, lacking evidence that the product may cause hazard to the human health and that this provokes in the deterioration or damage of the product, the United States Government should pay an insurance that protects the investment.

[1/] Emex = Packers of Mangoes for Export

2.2.2. Unión Agricola Estatal de Michoacán[1/]

- ✓ In case of detention of the shipment, lacking evidence that the product may cause hazard to the human health and that this provokes in the deterioration or damage of the product, the United States Government should pay an insurance that protects the investment.

- ✓ We do not agree with the application of unilateral measure in our country; we think that this might be a violation to the subscribed agreements of NAFTA for those countries who have signed this document.

- ✓ If this measure is taken without the agreement of our members, we propose that the mexican goverment should be tasked with the creation of the required mechanism for this regulation. We also consider that the implementations of these measures are a potential barrier and moreover for the comercial flow of our products.

- ✓ Our members and other export companies would like to ask for an extension of the period that you have suggested and also we would like to ask that the dissemination and training costs of these new regulations could be shared for all the people involved in the production and consumption chain.

- ✓ These regulations will affect our business, but specially they are going to discourage mexican exportations and agricultural business to the U.S.

- ✓ Fresh produce has a limited time of life and there is a time of transit that we have to consider to get to the U.S. With the implementation of these regulations contained in the Bioterrorism law, the stock life of our products will be dramatically reduced, having as result a lower quality and the economical value would be affected.

- ✓ It will be a great responsability for the Mexican government to defend the producers and exporters position at those important forums about this topic. We trust that our organization will support at every moment our interests as exporters and as mexicans.

2.3. Grupo Bimbo

These comments are submitted on behalf of Grupo Bimbo (GB), a company with assets in the USA such as Bimbo Bakeries USA. Our company is one of the leading baking companies in the American Continent, with operations in the U.S., Mexico, Central America, Peru, Colombia, Venezuela, Chile, Brasil, Argentina and Europe.

[1/] Unión Agrícola Estatal de Michoacán = Michoacan State Agricultural Union

Section 307 Title III Prior Notice of Imported Food

- ✓ The purpose of these comments is to voice our strong concern and opposition to the several parts of the agency's recent prior notice of imported food proposal.

- ✓ While GB appreciates the efforts FDA has put forth in trying to develop a comprehensive and thorough approach to prior notice of imported foods, none the less, this proposal clearly goes too far in prescribing **excessive requirements** that would negatively impact the efficient delivery of ingredients and processed foods into global commerce. **This proposal can hinder the smooth flow of imports and dramatically disrupt commerce as we know it today.**

- ✓ Continuation in this direction as the rule is finalized, would be devastating to the businesses of many bakers and their suppliers alike. We are questioning whether this proposal serves as an appropriate means to the stated goal and whether costs associated with such a proposal are outweighed by their usefulness in accomplishing the objectives of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

- ✓ GB understands that FDA's top priority must be to insure proper focus on the security of goods imported into the United States so that consumers can be assured of a wholesome and safe food supply. GB is hopeful that its comments addressing issues of workability and rational, efficient transport of ingredients and finished bakery products will assist the agency as it moves forward to finalize this important policy.

Barrier for a smooth commerce flow

- ✓ In the report language accompanying the Bioterrorism Act, Congressman Shimkus emphasized that it was the congressional intent for the Secretary of Health and Human Services (HHS) to exercise discretion to ensure that neither the requirements nor the timing of prior notice be more burdensome than necessary to provide for the ability of food port inspectional personnel, nor should such requirements become a barrier to the smooth flow of commerce. Further, the language directs the HHS Secretary to consider the effect on commerce of time periods; locations of various ports of entry; various modes of transportation and the types of food imported into the United States. Clearly the overly ambitious time constraints that are included in FDA's proposal attempts to micro-manage trade and will subsequently slow imports and interstate commerce significantly; crippling the global marketplace.

- ✓ Everyone should know what will happen in case of saturation of operations, what is the capacity in number of shipments, registration, and revision of documents per hour or working schedule that the FDA has considered? The law does not mention anything in this regard.

- ✓ We believe that the FDA has given little thought to the impact of its proposal on perishable products such as **bakery products**. With the anticipated dramatic slow down of trade and flow of products and ingredients across U.S. borders, **there will be a great impact on freshly baked products and "just in time" deliveries of vital ingredients that are currently a standard industry practice to assure timely product delivery.**

- ✓ Without having applied this law yet, we have had experiences where due to any special regulation of some type of product, the revisions have been translated in detentions of up to 10 days. In the particular case of GB, we handle mostly perishable products, consequently the 10 day detentions would make our export inoperative since it would be very difficult to commercialize our products after this time.

- ✓ Related to the point above, the proposed regulation states that once the FDA determines that the merchandise is subject to revision, it will be sent to an "In Bond" warehouse, where all the expenses will be charged of the exporter. In this sense, we would like to know the infrastructure that is considered in order to guarantee the sanitary levels, temperature conditions that the different types of merchandise will require, as well as the safety and responsibility in case of accidents, thefts, or any other contingencies. We strongly think that this measures should be an exception and that the good history of a company should be taken in account before proceeding to detain a shipment only because the FDA might have unsubstantiated suspicions coming from little mistakes in the filling of forms or by rumors that the FDA might pick up.

FDA Scheduling

- ✓ The FDA has to consider very carefully the revision time they have for all the shipments. The FDA should increase substantially the time scheduled for revisions during the day in the borders and consider late afternoon and night work for border authorities as well as FDA officers so the time for the revisions could be ample enough to expedite the process.

- ✓ Therefore, it becomes imperative for the FDA border inspectors to expand their current work schedule of Monday through Friday; under the new scheme, FDA boarder inspectors will be needed seven days per week, 24 hours per day.

- ✓ In order not to slow down the crossings, many additional inspectors and FDA office staff will be needed to support the infrastructure that FDA is proposing.

- ✓ Also, The knowledge of the schedules of all border FDA offices is important, so the FDA should be able to inform all interested parties on this.

Timing for Notices

- ✓ The Statutory language requires 8 hours minimum – five day maximum for notice; therefore, the 4 hour time frame that the working group was considering would not be acceptable under the statute. The likelihood of the statute being changed is basically nil. But the Act's accompanying report language emphasizes the congressional intent for the Secretary of HHS to exercise discretion to ensure that neither the requirements not the timing of prior notice be more burdensome than necessary to provide for the availability of food import inspectional personnel, nor should such requirements become a barrier to the smooth flow of commerce.

- ✓ By requiring notice by noon of the day before the anticipated importation, FDA will substantially increase the number of amendments and updates. This timing is not close enough and it would cause us to make amendments practically for each shipment, considering that sometimes we are subject to modifications for product availability at the plant, since the lots produced seldom can be exactly as the number requested for .

- ✓ Some of this issues make us very concerned about the workability of the system.

- ✓ In the case of food products produced Mexico, the time between the completion of production, and then it's loading and transportation to the U.S. port of entry, is often considerably less than the time required for prior notice. Because of the extensive data that FDA proposes to require in a prior notice, it will ordinarily not be possible for prior notice to be submitted before the transportation vehicle is loaded. Yet, given the short distances between many of these facilities and the U.S. border, the notice cannot possibly be submitted in time to permit the orderly movement of the vehicle to the border for clearance into the United States.

- ✓ Lets talk about an example: Envision a production facility located in Mexico approximately one hour south of the U.S. border. The facility runs two shifts and product is typically loaded immediately after production directly onto trucks for transportation to the United States. Under the proposal, the prior notice will need to be submitted by noon of the day before the truck is due to arrive at the port of entry. Yet, the prior notice would be required to contain, among other extraneous information, the lot or production codes of the article of food to be imported. In the scenario described, that information is not reasonably known until the truck is loaded. Even if the prior notice were filed immediately after the truck was loaded, the notice would not be effective for a day or more (a notice filed at 4 p.m. on Monday would not be timely for a Monday or Tuesday arrival at the port of entry).

- ✓ It is conceivable that the system that FDA has proposed could increase the risks to the security of the food supply, rather than add to it. If fully loaded trucks are required to delay their departure or arrival at ports of entry to comply with unreasonable prior notice requirements, the opportunity for malicious activity

involving the product on those trucks increases. In contrast, it is consistent with the objective of food security for the trucks to be loaded and then to proceed without interruption or delay to their destination.

✓ FDA appears to have recognized this problem, but its solution – the ability to anticipate the need for and to amend a notice – does not solve the problem, as it will be reviewed below.

Amendments

✓ We question also the workability of the amendments, because they require for food companies to have information about shipments before that information can reasonably by obtained and it does not permit them to amend a notice in a meaningful way, even when they do have the information.

✓ Assume that a facility one hour south of the border produces a variety of snack foods and that it transports its products to the United States by truck, several of which depart for the United States each day. The mix of products that is loaded onto each truck is determined by production schedules and orders from distributors and retailers. Typically, the items to be loaded and the exact quantity of each are not known until shortly before the truck arrives at the loading dock. Even if prior notice is provided at the first available opportunity, the notice will not be timely for at least a day (if the truck is loaded and the notice is filed before noon) or two days (in the case of trucks loaded after noon).

✓ Under the proposal, FDA would permit amendments related to common or usual name, trade or brand name, lot or production codes, and quantity. The ability to amend a prior notice can be very limited.

✓ Also we believe that this amendment should be done as many times as needed per item by the exporter, since there are many cases in which this will become imperative, such as: Last minute changes to the order to be shipped, changes in product codes because of this late changes in the order shipped, changes in transport trucks, etc.

✓ Just an example, there could be the case of a broken truck that needs to be changed in order to get the product to the border. If the prior notice was already amended, there wouldn't be a chance to amend it again because of the problem stated above.

✓ Furthermore, for each transport we handle from 30 to 50 different type of food products (mainly bakery and snack products) with different presentations. Preparing the amendment with its proper FDA code, would imply an additional administrative job that would originate a higher cost than the one we have today with our service providers, such as customs brokers. It is estimated that the documentation that the American customs broker presents nowadays to the U.S.

Customs and the FDA, might be tripled with the amendments we would have to prepare.

- ✓ Sometimes, in the Mexican border, the transportation is detained for the question of red lights or second revisions and this is unknown until the transportation is actually crossing the border. This would delay the transportation's arrival on the indicated time. Will that also be a cause for an amendment?

- ✓ It seems that many of those problems could be avoided if a more flexible notice period would be defined (four hours before anticipated arrival, for example). Moreover, FDA should provide for more flexibility in terms of the time of arrival at ports of entry, where the actual time differs from the anticipated. A shipment arriving just outside the window for updates should not be deemed to have an ineffective notice.

Prior Notice for each product

- ✓ As stated above, for each transport we handle from 30 to 50 different type of food products (mainly bakery and snack products) with different presentations. To prepare a Prior Notice for each type of product is unreasonable and it should be the possibility to have Prior Notices per shipments, and in the forms, there should be the possibility for listing in an annex all the items in that shipment, instead of having to do a Prior Notice per each type of product, as it seems to be the case on the proposed regulation.

FDA Feedback

- ✓ Once the notification is received via Internet by the FDA, a number is issued to the filing company, but what is the mechanism to inform the company that subjected the previous notification that the information submitted is without any problems? It would be terrible to have the surprise of the detention of perishable goods just because of an omission in the filling of the forms. It would really be important to enable by any way, that the FDA, in addition to sending the notification's receipt acknowledgement, sends us the approval, rejection or comments on the forms. In the other way, we as exporters would be subjected to receive feedback from the FDA until the merchandise arrives to the border, and in case the notification presented abnormalities, we could not fix it and therefore, we could not export the merchandise. The above would present average losses in the order of $15,000.00 USD per truck per day that does not cross the border. We handle as much as 150 trucks a week

Food Packaging, etc.

- ✓ GB notes that within the Report language that accompanied the final Bioterrorism Act, there was language that appears to express an intent that food packaging and other food contact substances not be subjected to the prior notification

requirements for imports, unless food is already packaged in it. Specifically the language offered by Congressman Shimkus said,

"Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food."

- ✓ The inclusion of food packaging and food contact substances such as equipment; replacement parts for machinery and sanitizing solvents greatly expands the breath of the proposed regulation and will unduly clog the ports of entry with hundreds of thousands of additional imports to be examined. This additional reporting will burden not only industry but will disproportionately burden FDA staff and resources that simply will not be able to swiftly and effectively move these product through ports of entry into interstate commerce. Many additional inspectors and FDA office staff will be needed to support the infrastructure that FDA is proposing

Inpack promotions

- ✓ In the export operations of companies such as ours, we perform several promotions a year. Many of this promotions consists of integrating a price (which can be in- pack) into the product that is sent from origin; such promotion does not go on sale and therefore it does not have any type of product code. It is important to point out here that it is not a food product either. It is not clear how should this be declared, if needed, in the prior notice form.

- ✓ Also, with the purpose of promoting the sale of any of our other products or for sampling purposes of a new one, we export from Mexico to our operations in the United States, products with "in packs" of other food products (for example, a sample of a new cookie). Must the products inside be subjected to different prior notice? If this different notice is not needed (which we hope), it is not clear how should this product inside has to be declared, in the prior notice form. You should consider that the main product could be form one type (for example a croissant) but the in-pack promotion could be something different (lets say, Gummy bears)

Existing International Trade Regulations

- ✓ GB is very concerned that FDA's new proposal is redundant based on existing U.S. Customs requirements. Since coordination of the two systems will not be available until at least 2005, that means double reporting work for industry and government reviewers.

- ✓ GB is very concerned that FDA's proposed rule for prior notice of imported foods appears to ignore the difference between sea/air ports and land border points. While it takes longer amounts of time for goods to be shipped great distances, it takes very little time for food to be shipped from Mexico into the United States.

Creating an immense, slow moving border between Mexico and the United States equates with creating borders between two states where commerce has been seamless in the past. Businesses are fully integrated on both sides of the border after many years of successful and cooperative development, supported by such government initiatives as the North American Free Trade Agreement.

- ✓ The possible cost on our exports is so overwhelming that many companies in Canada and Mexico are feeling this measures will act as a non-tariff barrier applied to imports to the United States, and become, without being its intent, a disloyal practice in commerce.

- ✓ The proposed rule could result in a barrier being erected at land borders that will cause severe damage to food businesses on both sides of the border. GB recommends that FDA study the details of the actual situation, mainly at the land borders so that its proposed rule allows an uninterrupted, efficient flow of perishable goods to continue.

- ✓ It's important that the FDA gives more consideration to reviewing international developments of trade security. GB strongly encourages FDA to work together with other trading partners to ensure that a fair and equitable food security system that supports international trade be developed among the nations

Samples

- ✓ The proposal seems to indicate that it will be required to perform a Prior Notice in case of sending samples not for sale purposes, but for presentation to clients, approvals, etc. This will be burdensome and impractical since these are handled by curriers such as Fedex or DHL. In the operation of companies such as GB, new products are launched and exported from Mexico to the USA and it is indispensable to send samples from Mexico with the purpose of presenting them to our clients and register them in self-service stores.

- ✓ We propose this type of shipments shouldn't need the prior notice up to certain size or weigth.

Consideration of Safe History

- ✓ While GB understands the importance of reviewing questionable shipments that are not well-documented, we believe that credit should be given to historically responsible foreign exporters and US importers who have demonstrated effective and successful systems of secure transport; their methods for an effective and safe routine should be studied and put into practice by others. Our company ships product and ingredients across the U.S. border every week in a responsible manner, and have done so for several years. FDA's final rule should recognize these efforts and include a provision that could serve as an incentive to importers who have proven themselves.

- ✓ Also it should be important to consider manufacturing companies abroad who work with US customs authorities on smuggling issues and which have quality assurance systems such as HACCP and which are certified by different well known organizations, such as the AIB (American Institute of Baking) and QBA (Quality Bakers of America).

Other issues to consider

- ✓ Another workability issue to consider is the possibility of "system terrorism". It seems that this system might be attacked somewhat easily by third parties, by registering a ghost facility an sending phony prior notices. This could jam the system if they were in large numbers, or if someone should send an alarm or rumor, the FDA would be chasing around shipments that really do not exist. These security issues should be addressed.

- ✓ A lot of export products go from Mexico to Canada but might stop in the US. We believe this issue should be taken in account in order to make more flexible this case.

- ✓ Also, it is proposed that for the Prior Notice, the following information should be included:
  Country of origin
  Transporters data
  Producer/Exporter data
  General information of product to be Exported based on the first 4 or 6 digits of the Tariff.

- ✓ With the latter information the FDA could have advanced data of the product's nature in order to be able to have its specialists ready in case they had to perform any revision.

- ✓ And for the exact and precise information about the amounts and the product's nature, it is proposed to continue using the ACS system and Oasis, since it is possible to have with it the exact information (amounts, FDA codes) and avoid sending this in additional manner to the electronic means to the FDA, who will doubtlessly have to have in their turn a personnel structure bigger than the amount they have today in order to enter all this information twice.

2.2. Sugar Industry

Cámara de la Industria Azucarera y Alcoholera[1/]

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[1/] Cámara de la Industria Azucarera y Alcoholera = Sugar and Alcohol Industry Chamber

- ✓ Although the U.S.A. has the right to apply a law that provides security, it also has to make sure that it does not violate other current laws in U.S.A. as well as in Mexico, specifically NAFTA.

- ✓ Nevertheless, section 307, relative to the shipping notice, does not require the u.s. suppliers of food products to comply with it, but it is a requisite for the suppliers of Mexican food products, thereby violating the fundamental principle of "non discriminatory treatment" agreed in NAFTA.

- ✓ The concept of "non discriminatory treatment" requires that the signatory nations of NAFTA treat the companies of the other parties as if they were companies of their own country, and prohibits requiring the companies of the other parties to fulfill additional administrative loads, quality standards, labeling, etc., that are not required to their own companies.

- ✓ It is therefore imperative that the U.S.A. modifies its proposed law; in such a way that section 307 will not apply to Mexico or Canada, and exempts them of the section 307 shipping notice requirements, like the U.S. companies.

- ✓ The Mexican sugar chamber shares the security concerns with the U.S.A. government, but we don't want to see this unilateral action flagrantly violate international laws such as NAFTA and the WTO.

Nacional Agricultural Council

Fax Cover **Number of pages including cover ___17___**

For:	**Dockets and Management Branch (HFA 305)**
Organization:	**Food and Drug Administration**
From:	**Mr. Armando Paredes, President** **Nacional Agricultural Council**
Subject:	**Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**
Date:	**April 3rd, 2003**

Comments ___X____

To whom it may concern:

Attach to this fax cover we send comments about the Bioterrorism Act's Title III section 307 received for some of our members

Sincerely

Armando Paredes, President
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